

National List -- Preamble

Subpart G Administrative

The National List of Allowed and Prohibited Substances

Description of Regulations

General Requirements

This subpart contains criteria for determining which substances and ingredients are allowed or prohibited in products to be sold, labeled, or represented as "organic" or "made with organic (specified ingredients or food group(s))." It establishes the National List of Allowed and Prohibited Substances (National List) and identifies specific substances which may or may not be used in organic production and handling operations. Sections 6504, 6510, 6517, and 6518 of the Organic Foods Production Act (OFPA) of 1990 provide the Secretary with the authority to develop the National List. The contents of the National List are based upon a Proposed National List, with annotations, as recommended to the Secretary by the National Organic Standards Board (NOSB). The NOSB is established by the OFPA to advise the Secretary on all aspects of the National Organic Program (NOP). The OFPA prohibits synthetic substances in the production and handling of organically produced agricultural products unless such synthetic substances are placed on the National List.

Substances appearing on the National List are designated using the following classifications:

1. Synthetic substances allowed for use in organic crop production
2. Nonsynthetic substances prohibited for use in organic crop production
3. Synthetic substances allowed for use in organic livestock production
4. Nonsynthetic substances prohibited for use in organic livestock production
5. Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))"
6. Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as organic" or "made with organic (specified ingredients or food group(s))"

This subpart also outlines procedures through which an individual may petition the Secretary to evaluate substances for developing proposed National List amendments and deletions.

The NOSB is responsible for making the recommendation of whether a substance is suitable for use in organic production and handling. The OFPA allows the NOSB to develop substance recommendations and annotations and forward to the Secretary a Proposed National List and any subsequent proposed amendments. We have made every effort to ensure the National List in this final rule corresponds to the recommendations on allowed and prohibited substances made by the NOSB. In developing their recommendations, the NOSB evaluates synthetic substances for the National List utilizing the criteria stipulated by the Act. Additionally, criteria for evaluating synthetic processing ingredients have been implemented by the NOSB. These criteria are an interpretation and application of the general evaluation criteria for synthetic substances contained in the OFPA that the NOSB will apply to processing aids and adjuvants. The NOSB adopted these criteria as internal guidelines for evaluating processing aids and adjuvants. The adopted

criteria do not supersede the criteria contained in the OFPA or replace the Food and Drug Administration's (FDA) regulations related to food additives and generally recognized as safe (GRAS) substances. The NOSB has also provided recommendations for the use of synthetic inert ingredients in formulated pesticide products used as production inputs in organic crop or livestock operations. The Environmental Protection Agency (EPA) regulates and maintains the EPA Lists of Inert ingredients used for pesticide. In this final rule, EPA Inerts List 1 and 2 are prohibited, EPA List 3 is also prohibited unless specifically recommended as allowed by the NOSB, and EPA List 4 Inerts are allowed unless specifically prohibited.

In this final rule, only EPA List 4 Inerts are allowed as ingredients in formulated pesticide products used in organic crop and livestock production. The allowance for EPA List 4 Inerts only applies to pesticide formulations. Synthetic ingredients in any formulated products used as organic production inputs, including pesticides, fertilizers, animal drugs, and feeds, must be included on the National List. As sanctioned by OFPA, synthetic substances can be used in organic production and handling as long as they appear on the National List. The organic industry should clearly understand that NOSB evaluation of the wide variety of inert ingredients and other nonactive substances will require considerable coordination between the NOP, the NOSB, and industry. Materials review can be anticipated as one of the NOSB's primary activities during NOP implementation. Considering the critical nature of this task, the organic industry should make a collaborative effort to prioritize for NOSB review those substances that are essential to organic production and handling. The development and maintenance of the National List has been and will be designed to allow the use of a minimal number of synthetic substances that are acceptable to the organic industry and meet the OFPA criteria.

We expect the maintenance of the National List to be a dynamic process. We anticipate that decisions on substance petitions for the inclusion on or deletion from the National List will be made on an annual basis. Any person seeking a change in the National List should request a copy of the petition procedures that were published in the Federal Register (65 Fed Reg 43259 - 43261) on July 13, 2000, from the NOP. The National List petition process contact information is: Program Manager, National Organic Program, USDA/AMS/TMP/NOP, Room 2945-S, Ag Stop 0268, P.O. Box 96456, Washington, DC 20090-6456 or visit the NOP website: www.ams.usda.gov/nop. Substances petitioned for inclusion on the National List will be reviewed by the NOSB, which will forward a recommendation to the Secretary. Any amendments to the National List will require rulemaking and must be published for comment in the Federal Register.

Nothing in this subpart alters the authority of other Federal agencies to regulate substances appearing on the National List. FDA issues regulations for the safe use of substances in food production and processing. USDA's Food Safety and Inspection Service (FSIS) has the authority to determine efficacy and suitability regarding the production and processing of meat, poultry, and egg products. FDA and FSIS restrictions on use or combinations of food additives or GRAS substances take precedence over the approved and prohibited uses specified in this final rule. In other words, any combinations of substances in food processing not already addressed in FDA and FSIS regulations must be approved by FDA and FSIS prior to use. FDA and FSIS regulations can be amended from time to time under their rulemaking procedures, and conditions of safe use of food additives and GRAS substances can be revised by the amendment. It is important that certified organic producers and handlers of both crop and livestock products consult with FDA regulations in 21 CFR parts 170 through 199 and FSIS regulations in this regard. All feeds, feed ingredients, and additives for feeds used in the production of livestock in an organic operation must comply with the Federal Food, Drug, and Cosmetic Act (FFDCA). Animal feed labeling requirements are published in 21 CFR Part 501, and new animal drug requirements and a listing of approved animal drugs are published in 21 CFR Parts 510-558. Food (feed) additive requirements, a list of approved food (feed) additives generally recognized as safe substances, substances affirmed as GRAS, and substances prohibited from use in animal food or feed are published in 21 CFR 570-571, 21 CFR 573, 21 CFR 582, 21 CFR 584, and 21 CFR 589, respectively. Furthermore, the Food and Drug Administration has worked closely with the

Association of American Feed Control Officials (AAFCO) and recognizes the list of additives and feedstuffs published in the AAFCO Official Publication, which is updated annually.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA regulates the use of all pesticide products, including those that may be approved for use in the NOP. In registering a pesticide under FIFRA, EPA approves the uses of each pesticide product. It is a violation of FIFRA to use a registered product in a manner inconsistent with its labeling. The fact that a substance is on the National List does not authorize use or a pesticide product for that use if the pesticide product label does not include that use. If the National List and the pesticide labeling conflict, the pesticide labeling takes precedence and may prohibit a practice allowed on the National List.

National List - Changes Based On Comments

This subpart differs from the proposal in several respects as follows:

(1) Comprehensive Prohibition on Excluded Methods. Many commenters supported a comprehensive prohibition on the use of excluded methods in organic production and handling. These commenters stated that the proposed language on excluded methods could have allowed some uses since the general prohibition described in section 205.301 of the proposed rule could be interpreted as applying only to multiingredient products. In order to provide a comprehensive prohibition on the use of excluded methods, we incorporated a new provision within section 205.105. A more comprehensive discussion of this issue is found in subpart B, Applicability.

(2) Substance Evaluation Criteria for the National List. Commenters stated that the final rule should include in the regulation text the evaluation criteria utilized by the NOSB for the development of substance recommendations. We agree, and we have inserted the substance evaluation criteria developed by the NOSB for processing ingredients and cited the criteria within the Act (7 U.S.C. 6518(m)) for crops and livestock production as new provisions for section 205.600, which is now entitled "Evaluation criteria for allowed and prohibited substances, methods, and ingredients."

(3) Substances Approved for Inclusion on the National List. Commenters stated that the National List did not contain all of the substances recommended by the NOSB for inclusion on the National List of Allowed and Prohibited Substances. We agree and have added the following substances consistent with the most recent NOSB recommendations:

Crop Production:

Lime sulfur as a plant disease control substance

Elemental sulfur as a plant or soil amendment

Copper as a plant or soil micronutrient

Streptomycin sulfate as plant disease control substances with the annotation " for fire blight control in apples and pears only"

Terramycin (oxytetracycline calcium complex) as a plant disease control substance with the annotation "for fire blight control only"

Magnesium sulfate as a plant or soil amendment with the annotation "allowed with a documented soil deficiency"

Ethylene as a plant growth regulator, with the annotation "for regulation of pineapple flowering"

We have added sodium nitrate and potassium chloride to the National List as nonsynthetic substances prohibited for use in crop production unless used in accordance with the substance annotations. Sodium nitrate is prohibited unless use is restricted to no more than 20 percent of the crop's total nitrogen requirement. Potassium chloride is prohibited unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil. These additions are discussed further in item 3 under Changes Based on Comments, subpart C.

Livestock Production:

Oxytocin with the annotation "for use in postparturition therapeutic applications"

EPA List 4 inert ingredients as synthetic inert ingredients for use with nonsynthetic substances or synthetic substances allowed in organic livestock production.

Several commenters recommended that the final rule should specify which nonsynthetic substances are prohibited for use in livestock production. These commenters stated that the proposed rule prohibited six such substances for use in crop production and maintained that an analogous list for livestock operations would be beneficial. Of the six nonsynthetic substances in the proposed rule prohibited for use in crop production, four were based on NOSB recommendations (strychnine, tobacco dust, sodium fluoaluminate (mined), and ash from burning manure) and two were based on statutory provisions in the OFPA (arsenic and lead salts). After reviewing these substances and the NOSB recommendations, we determined that the prohibition for one, strychnine, also applies to livestock production. Individuals may petition the NOSB to have additional nonsynthetic substances prohibited for use in organic crop and livestock production.

Organic Handling (Processing):

Tribasic calcium phosphate

Nonsynthetic colors

Flavors, with the annotation "nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservatives"

Nonsynthetic waxes, carnauba wax, wood resin

Cornstarch (native), gums, kelp, lecithin and pectin were moved from section 205.605 to section 205.606

(4) Substance Removed from the National List. Commenters stated that certain substances on the National List in the proposed rule had not been recommended by the NOSB. We agree with the comment that the NOSB did not recommend that magnesium should be allowed as a plant or soil micronutrient and have removed it from the National List.

(5) Changes in Substance Annotations on the National List. Commenters stated that certain annotations in the proposed rule did not capture the precise recommendations of the NOSB. We agree and have amended the annotations within the National List as follows:

The annotation for hydrated lime as a plant disease control substance now states, "must be used in a manner that minimizes accumulation of copper in the soil."

The annotation for horticultural oils as an insecticide substance and as a plant disease control substance now states, "Narrow range oils as dormant, suffocating, and summer oils."

The annotation for hydrated lime in livestock production now states, "not permitted for soil application or to cauterize physical alterations or deodorize animal wastes."

The annotation for the allowed synthetic parasiticide Ivermectin has been modified to state that the substance may not be used during the lactation period of breeding stock.

The annotation for trace minerals and vitamins allowed as feed additives has been modified and now states, "used for enrichment or fortification when FDA approved."

The annotation for magnesium sulfate in organic handling now states, "nonsynthetic sources only."

The annotation for EPA List 4 Inerts allowed in crop and livestock production has been modified to state, "...for use with nonsynthetic substances or synthetic substances listed in this section..."

(6) Sulfur Dioxide for Organic Wines. Many commenters recommended that this final rule should allow for the use of sulfur dioxide in wine labeled "made with organic grapes." They argued that sulfur dioxide is necessary in organic wine production and that prohibiting its use would have a negative impact on organic grape production and wineries that produce wine labeled "made with organic grapes." The prohibition on the use of sulfur dioxide in the proposed rule was based upon the requirement in the Act that prohibited the addition of sulfites to organically produced foods. However, a change in the Act now allows the use of sulfites in wine labeled as "made with organic grapes." Therefore, we have added sulfur dioxide to the National List with the annotation, "for use only in wine labeled 'made with organic grapes,' Provided, That, total sulfite concentration does not exceed 100 ppm." The label for the wine must indicate the presence of sulfites. This addition to the National List is also in agreement with the NOSB recommendation for allowing the use of sulfur dioxide in producing wine to be labeled as "made with organic grapes."

National List - Changes Requested But Not Made

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) Restructuring the National List. Commenters requested a restructuring of the National List to improve its clarity and ease of use. Some of the commenters asked for minor changes involving the wording of section titles. Other commenters were opposed to the categories used in the National List because the categories are not in compliance with the Act. In its June 2000 meeting, the NOSB asked the NOP to review a proposal from a research institute proposing that processing materials for the National List be categorized according to industry standards. This proposal recommended including new sections for substances used in "made with..." and substances used in the 5-percent nonorganic portion of "organic" multiingredient products. We agree that the present structure of the National List may not have optimum clarity and ease of use. However, extensive restructuring of the National List without additional NOSB consideration and public discussion would be a significant variation from the policy that established the National List for this final rule. The NOP will work with the NOSB and the public to refine the National list consistent with industry norms and public expectations.

(2) Use of EPA List 4 Inerts. The proposed rule allowed EPA List 4 Inerts to be used as synthetic inert ingredients with allowed synthetic active ingredients in crop production. Some commenters stated that certain substances among the EPA List 4 inerts should not be allowed in organic production. Some commenters went further and recommended that the allowance for synthetic

inert ingredients should be limited to the subset of materials that the EPA designates as List 4A. We do not agree with these commenters and have retained the allowance for all inerts included on EPA List 4. List 4 inerts are classified by EPA as those of "minimal concern" and, after continuing consultation with EPA, we believe there is no justification for a further restriction to List 4A. If commenters believe that a particular List 4 inert should not be allowed in formulated products used in organic production, they can petition the NOSB to have that substance prohibited.

(3) Removing Vaccines from the National List. Some commenters asserted that vaccines should not be included on the National List because the NOSB had never favorably recommended their use in livestock production. However, the OFPA authorizes the use of vaccines, and in 1995, the NOSB recommended allowing their use. The NOSB stated that use of vaccines may be necessary to ensure the health of the animal and to remain in compliance with Federal, State, or regional regulations. We agree with the NOSB's recommendation and have retained vaccines as an allowed substance in livestock medication.

(4) Adding Amino Acids to the National List. Some commenters recommended that amino acids should be added to the National List as allowed synthetic substances for livestock production. We have not added amino acids to the National List because the NOSB has not recommended that they should be allowed. This subject is discussed further in item 4, Livestock - Changes Based on Comments, subpart C.

(5) Creating a Category for Prohibited Nonsynthetic Seed Treatments. A commenter stated that the National List of nonsynthetic substances prohibited for use in crop production should include provisions for seed treated with a nonsynthetic substance. This commenter stated that the final rule should acknowledge that a nonsynthetic seed treatment could be prohibited on the National List. We do not believe it is necessary to include a separate category for seed treatments under the prohibited nonsynthetic section of the National List. An individual may petition the NOSB to have a particular nonsynthetic seed treatments placed on the prohibited list without creating a new category for seed treatments.

(6) Creating a Category for Treated Seed and Toxins Derived from Bacteria. Commenters stated that the National List of synthetic substances allowed in crop production should include categories for treated seed and toxins derived from bacteria. These commenters stated that these categories are sanctioned by the OFPA, and failure to consider them would place a significant burden on organic producers. We believe it is unnecessary to include these categories on the National List. Specific substances from these categories could be incorporated in existing categories that reflect their function, such as plant disease control or insecticide. An individual may submit petitions to the NOSB to have specific substances from these categories considered for inclusion on the National List.

(7) Remove Categories for Feed Supplements. A commenter stated that it was inappropriate for the National List of synthetic substances allowed in livestock production to contain categories for feed supplements and feed additives because they are not authorized in the OFPA. We disagree with this commenter because the identification of categories on the National List does not mean that all substances within that category are allowed. The categories help to clarify which types of materials may be included on the National List. The substances included under the categories of feed supplements and feed additives were recommended by the NOSB and added to the National List with the Secretary's approval.

(8) Neurotoxic Substances on the National List. Many commenters requested that the NOP remove particular substances from section 205.605 of the National List. They stated these substances were sources of neurotoxic compounds that negatively effect human health. The substances cited were yeast (autolysate and brewers), carrageenan, and enzymes. Moreover, these commenters argued against including on the National List some amino acids or their

derivatives which the commenters claim have neurotoxic side effects. These commenters requested that amino acids should be prohibited from the National List due to the possibility that neurotoxic substances could be utilized for either organic agricultural production or handling.

We do not agree with the requests of the commenters and we have not made the requested changes. There are no amino acids currently on the National List; therefore, synthetic sources of amino acids are prohibited. Unless recommended for use by the NOSB, synthetic amino acids will not be included on the National List. The NOP has established a petition process for substances to be evaluated for inclusion on or removal from the National List of Allowed and Prohibited Substances in organic production and handling. Anyone seeking to have a particular substance removed from the National List may file a substance petition to amend the National List.

(9) EPA List 4 Inerts for Organic Processing. A few commenters recommended that substances in EPA List 4 inerts that are allowed for use in crop production also be allowed for use as processing materials. We do not agree, and we have not included EPA List 4 Inerts on the National List for organic handling. Inerts listed on EPA List 4 have been evaluated and approved for use in pesticide formulations, not for use as processing materials. Inerts that are included on EPA List 4 would have to be further evaluated to determine whether such materials meet the criteria for inclusion on the National List.

(10) Modifying Annotations of Organic Processing Substances. One commenter requested that the Department modify the annotation for phosphoric acid to include its use as a processing aid. We have not made the suggested change. Any change in the annotation of a substance can only occur through an NOSB recommendation. Individuals or groups can use the petition process to submit substance petitions to the NOSB for the evaluation to be included on or removed from the National List.

(11) Nutritional Supplementation of Organic Foods. Some commenters asserted that 21 CFR 104.20 is not an adequate stand-alone reference for nutritional supplementation of organic foods. As a result, these commenters recommended that the final rule include as additional cites 21 CFR 101.9(c)(8) for FDA-regulated foods and 9 CFR 317.30(c), 318.409(c)(8) for foods regulated by FSIS to support 21 CFR 104.20. We did not implement the suggested changes of the commenters. Section 205.605(b)(20) in the proposed rule allowed the use of synthetic nutrient vitamins and minerals to be used in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods, as ingredients in processed products to be sold as "organic" or "made with..." The commenters recommended cites, 21 CFR 101.9(c)(8) for FDA-regulated foods and 9 CFR 317.30(c); section 318.409(c)(8) did not provide provisions for nutritional supplementation of foods. Instead, these suggested cites were particularly aimed toward: (1) the declaration of nutrition information on the label and in labeling of a food; (2) labeling, marking devices, and containers; (3) entry into official establishments; and (4) reinspection and preparation of products. The NOP, in consultation with FDA, considers 21 CFR 104.20 to be the most appropriate reference regarding nutritional supplementation for organic foods.

(12) National List Petition Process as Part of the Final Rule.

Commenters have requested that the National List Petition Process, approved by the NOSB at its June 2000 meeting (and published in the Federal Register on July 13, 2000), be included in the final rule. We do not agree with the commenters, and we have retained the National List Petition Process regulation language from the proposed rule. We have separated the specific petition process from the regulation to provide for maximum flexibility to change and clarify the petition process to accommodate new considerations developed during the NOP implementation. If this process were part of this final rule, updates to the petition process would require notice and comment rulemaking. Any changes in the National List that may be a result of the petition process, however, would require notice and comment rulemaking.

(13) Nonapproved Substance Amendments to the National List. Commenters also requested to have many substances that are not on the National List and that have not been recommended by the NOSB for use in organic production and handling be added to the National List. We do not agree. Amendments to the National List must be petitioned for NOSB consideration, must have an NOSB recommendation, and must be published for public comment in the Federal Register.

National List - Clarifications

Clarification is given on the following issues raised by commenters as follows:

(1) Inerts Use in Botanical or Microbial Pesticides. Commenters expressed concern that the prohibition on the use of EPA List 3 inerts would prevent organic producers from using certain botanical or microbial formulated products that are currently allowed under some certification programs. These commenters requested that the NOP and the NOSB expedite the evaluation of List 3 inerts used in nonsynthetic formulated products to prevent the loss of certain formulated products. The prohibition of List 3 inerts was based on the recommendation of the NOSB to add only those substances from List 4 to the National List. The NOSB also recommended that individual inert substances included on List 3 could be petitioned for addition to the National List. The NOP has requested that the NOSB identify for expedited review those List 3 inerts that are most important in formulated products used in organic production. Individuals may petition to have these inerts considered for inclusion on the National List. Additionally, the NOP will work with the EPA and the registrants of formulated products to expedite review of List 3 inerts currently included in formulated products used in organic production. Unless List 3 inerts are moved to List 4 or individually added to the National List, they are prohibited for use in organic production.

(2) Prohibiting Ash, Grit, and Screenings Derived from Sewage Sludge. Many commenters recommended that the ash, grit, and screenings derived from the production of sewage sludge should be added to the National List as nonsynthetic materials prohibited for use in crop production. While the use of sewage sludge, including ash, grit, and screenings, is prohibited in organic production, we did not add them to the National List as prohibited nonsynthetic substances. This subject is discussed further under subpart A, Definitions - Changes Requested But Not Made.

(3) Allowed Uses for Pheromones. Some commenters were concerned that the annotation for using pheromones as "insect attractants" was too limiting and would not include uses such as mating disruption, trapping, and monitoring. The annotation for pheromones does not preclude any use for a pheromone that is otherwise allowed by Federal, State, or local regulation.

(4) Nonagricultural Products as Livestock Feed Ingredients. Some commenters questioned whether nonsynthetic, nonagricultural substances such as fishmeal and crushed oyster shell needed to be added to the National List to be used in livestock feed. Nonsynthetic substances do not have to appear on the National List and may be used in organic livestock feed, provided that they are used in compliance with the FFDCFA. This subject is discussed further under item 4, Livestock - Changes Based on Comments, subpart C.

(5) Chlorine Disinfectant Limit Annotation for Organic Production and Handling. Some commenters requested clarification on the annotation for using chlorine materials as an allowed synthetic substance in crop and handling operations. The annotation in the proposed rule, which has been retained in the final rule, stated that "residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Water Drinking Act." With this annotation, the residual chlorine levels at the point where the waste water stream leaves the production or handling operation must meet limits under the Safe Drinking Water Act.

(6) Tobacco Use in Organic Production. One commenter questioned whether forms of tobacco other than tobacco dust, such as water extracts or smoke, were prohibited nonsynthetic substances. The technical advisory panel (TAP) review on which the NOSB based its recommendation to prohibit tobacco dust identified nicotine sulfate as the active ingredient. Therefore, any substance containing nicotine sulfate as an active ingredient is prohibited in crop production.

(7) Nonsynthetic Agricultural Processing Aids on the National List. A commenter requested clarification from the NOP on whether processing aids (e.g., defoaming agents), which are nonsynthetic and nonorganic agricultural substances (e.g., soybean oil), must appear on the National List when used in processing. In this regulation, a nonsynthetic and nonorganic agricultural product, such as soybean oil, used as a processing aid does not have to appear on the National List. Such products are included in the provision in section 205.606 that nonorganically produced agricultural products may be used in accordance with any applicable restrictions when the substance is not commercially available in organic form.

(8) Transparency of the National List Petition Process. Some commenters stated the petition process for amending the National List appears to have limited public access and should be more transparent. These commenters advocate that any amendments to the National List should be subject to notice and comment. They also requested clarity on how petitions are prioritized and reviewed and the timeframes for review. Additionally, these commenters asked the NOP to expedite the review of materials for the National List. On July 13, 2000, AMS published in the Federal Register (Vol. 65, 43259-43261) guidelines for submitting petitions for the evaluations of substances for the addition to or removal from the National List. In this notice, the NOP stated that most petition information is available for public inspection with the exception of information considered to be "confidential business information." The notice also specified that any changes to the National List must be published in the Federal Register for public comment. The published petition notice has also provided an indication to the industry about the urgency of the need for substance review and that the industry should provide pertinent information to the NOSB to expedite the review of materials not on the National List.